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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,089	NANDY ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are pending.

2. Applicant's election with traverse of Group II, claims 10-13 and the species of SEQ ID NO:2 in the reply filed on 08/19/2008 is acknowledged. The traversal is on the ground(s) that:

> "The requirement for restriction is respectfully traversed insofar as the Office Action has not demonstrated that an undue searching burden would be required to examine all groups and certainly not to examine at least more than one of the groups (for example, Groups I and III, which are *generically* directed to the molecules of the present invention and method(s) for the production thereof and/or use thereof). For example, Applicants' specification expressly teaches that the nucleic acid molecules of Group I and vaccines/pharmaceutical compositions comprising such polynucleotides encode the polypeptide product(s) of the elected Group II. A search of the two Groups would not constitute undue burden. "If search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct invention." (Emphasis added.) See, M.P.E.P. ~803.
>
> Regarding Group III, claim 14, which is directed to a process of using the product of elected Group II, reference is made to the decisions in In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995), and In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996). The Commissioner's comments thereon in 1184 TMOG 86, March 26, 1996, indicate that, where product and process claims in the same application have been restricted and the elected product claim has been found allowable, withdrawn process claims including the limitations of the allowed product claim will be rejoined into the application and fully examined in that same application. It is respectfully submitted that the process claims herein should be rejoined and fully examined at such time as the product claim is found allowable.
>
> The requirement for election of species is traversed insofar as the Office Action has not demonstrated that it would constitute undue burden to examine more than one polypeptide sequence(s) which comprise the structural features of the claimed group 4 major allergens from cereals *(Triticeae)*. To this end, Applicants cordially invite the Examiner to review the disclosure contained in the paragraph bridging page 4 lines 10-35 of the present specification and the disclosure contained in the sequence listing page."

This is not found persuasive because the structures of polypeptides and nucleic acids are completely different and require separate sequence searches. Further, patent and non-patent literature searches of nucleic acids encoding polypeptides and the polypeptides themselves are not commensurate in scope, given the disclosure in any one prior art reference. In addition, recombinant production of polypeptides requires a search of nucleic acids. Therefore, the search

required for a method of production of a polypeptide and is a separate search from that of the polypeptide.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-9 and 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/19/2008.

4. Claims 10-13 are currently under examination as they read on the polypeptide of SEQ ID NO 2 with or without the signal sequence and a pharmaceutical composition thereof.

5. Applicant's IDS document filed on 06/15/2006 is acknowledged. Reference to XP002325590, XP002325591, XP002332685, XP002332686 and XP002332687 have been crossed off because they are improper citations for the listed EMBL Accession Number references. The proper corresponding EMBL Accession Numbers have been added.

Claim Objections

6. Claims 10 and 11 are objected to because of the following informalities:

A. Claim 10 is dependent upon non-elected base claim 1.

B. Claim 11 is not in proper sentence or Markush format. If Applicant amends the claims and maintains the bulleted recitations in claim 11, then Applicant should amend those recitations to start with letters instead of bullets. Appropriate correction is required.

Correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations of a "polypeptide corresponding to" and "in accordance with" in claim 10 and "a polypeptide corresponding to" and "amino acid sequences according to" of claim 11 and "according to" in claims 12-13 are indefinite because the definitions of "corresponding to", "in accordance with" and "according to" are unclear. A small peptide may correspond or be in accordance with short subsequences of the recited polypeptides and be encompassed by the instant claim recitation. At the same time, the words corresponding and accordance do not necessarily mean sequence identity, opening up the claims to read on polypeptides that have a relationship to the recited sequences. Correction is required.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 10-13 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for : the polypeptide encoded by the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof, the specification does not provide reasonable enablement for : a polypeptide **corresponding to one of the amino acid sequences in accordance with** SEQ ID NO 2, 4, 6, 8 and 10, which is encoded by a DNA sequence according to claim 1 of claim 10; **a polypeptide corresponding to** the mature allergen of the amino acid sequences according to Claim 10, selected from the following group of amino acid sequences -one of **the amino acid sequences in accordance with SEQ ID NO 2, 4, or 6, beginning with amino acid 23**, -one of **the amino acid sequences in accordance with SEQ ID NO 8 or 10, beginning with amino acid 22** of claim 11; A polypeptide according to Claim 10 **as medicament** of claim 12; and **a pharmaceutical composition** comprising at least one polypeptide according to Claim 12 and

optionally further active ingredients and/or adjuvants **for the diagnosis and/or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21

amino acid signal peptide; the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof.

The recitations of a "polypeptide corresponding to" and "in accordance with" in claim 10 and "a polypeptide corresponding to" and "amino acid sequences according to" of claim 11 and "according to" in claims 12-13 open up the claimed polypeptides to encompass any small peptide that corresponds or is in accordance with short subsequences of the recited polypeptides. The terms corresponding and accordance do not necessarily mean sequence identity and open up the claims to read on polypeptides that have any relationship to the recited sequences. The specification has not adequately disclosed the use of the genus of polypeptides encompassed by the instant claim recitations for use in the claimed invention.

The recitation of "beginning with amino acid" in claim11 encompasses all subsequences of the recited sequences which begin with that amino acid. However, the specification has not adequately disclosed every fragment of the polypeptides of SEQ ID NOs 2, 4, 6, 8, or 10 beginning with amino acid 23 or 22 for use in the claimed method for therapy and diagnosis of allergies. One of ordinary skill in the art would be required to perform undue experimentation to use the genus of polypeptides and peptides encompassed by the instant claim recitation.

Also at issue is whether or not the claimed composition would function as a medicament and pharmaceutical composition. The specification discloses the use of pharmaceutical composition for therapy, but fails to disclose an animal model that when given the recited pharmaceutical composition/medicament had a statistically significant reduction in allergic symptoms compared to control. The art of allergen immunotherapy as taught by Tarzi et al.

(PTO-892; Reference U) teaches that whole allergen immunotherapy is unpredictable due to the retention of B-ell epitopes within the allergen which confers a risk of IgE-mediated potentially life-threatening systemic reactions (In particular, paragraph spanning pages 617-618, whole document) In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical compositions are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Substantiating evidence may be in the form of animal tests, which constitute recognized screening procedures with clear relevance to efficacy in humans. See Ex parte Krepelka, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein. Ex parte Maas, 9 USPQ2d 1746.

Although, the specification describes *in vitro* allergen cloning and sequencing experiments, there is no correlation on this record between the in vitro studies and the various methods of treating allergies in currently available form for humans or animals. It is not enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to efficacy in humans or animals. Ex parte Maas, 9 USPQ2d 1746.

Reasonable correlation must exist between the scope of the claims and scope of the

enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : the polypeptide encoded by the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof.

Applicant is not in possession of a polypeptide **corresponding to one of the amino acid sequences in accordance with** SEQ ID NO 2, 4, 6, 8 and 10, which is encoded by a DNA sequence according to claim 1 of claim 10; and **a polypeptide corresponding to** the mature allergen of the amino acid sequences according to Claim 10, selected from the following group

of amino acid sequences -one of **the amino acid sequences in accordance with SEQ ID NO 2, 4, or 6, beginning with amino acid 23**, -one of **the amino acid sequences in accordance with SEQ ID NO 8 or 10, beginning with amino acid 22** of claim 11.

Applicant has disclosed only the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof; therefore, the skilled artisan cannot envision all the contemplated polypeptide, medicament and pharmaceutical composition possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional

characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL Accession No AJ862830 (Reference 7 on the IDS filed on 06/15/2008).

EMBL Accession No AJ862830 teaches a sequence corresponding 100% over length and sequence to instant SEQ ID NO: 2.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

14. Claims 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL Accession No AJ862831 (Reference 8 on the IDS filed on 06/15/2008).

EMBL Accession No AJ862831 teaches a sequence corresponding 100% over length and sequence to instant SEQ ID NO: 4.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

15. Claims 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL Accession No AJ862834 (Reference 9 on the IDS filed on 06/15/2008).

EMBL Accession No AJ862834 teaches a sequence corresponding 100% over length and sequence to instant SEQ ID NO: 6.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

16. Claims 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL Accession No AJ862832 (Reference 10 on the IDS filed on 06/15/2008).

EMBL Accession No AJ862832 teaches a sequence corresponding 100% over length and sequence to instant SEQ ID NO: 8.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

17. Claims 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL Accession No AJ862833 (Reference 11 on the IDS filed on 06/15/2008).

EMBL Accession No AJ862833 teaches a sequence corresponding 100% over length and sequence to instant SEQ ID NO: 10.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

18. Claims 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004/000881 (Reference 2 on the IDS filed on 06/15/2006) and the corresponding U.S. Patent Application Publication 206/0177470 A1 (PTO-892; Reference A) as evidenced by the specification on page 3, lines 35-36 and page 4, lines 2-3 and 26-29.

U.S. Patent Application Publication 2006/0177470 A1 teaches a Group IV allergen from Triticum aestivum for use as a medicament in a pharmaceutical composition further comprising active ingredients for the diagnosis or treatment of allergies in the triggering of which group 4 allergens (In particular, paragraphs [0047] and [0072]- [0076]).

The specification teaches on page 3, lines 35-36 and page 4, lines 2-3 and 26-29 that Tri a 4 is the Group 4 allergen of Triticum *aestivum* having the amino acid sequence of SEQ ID NO:8

or SEQ ID NO:10. The reference teaches the same isolated allergen from the same source, so the resulting allergen must necessarily have the sequence of SEQ ID NO:8 or SEQ ID NO:10.

Claims 10-13 are included in this rejection because the recitation of the amino acid sequences in accordance with SEQ ID NO 8 and 10 in claim 10 and the amino acid sequences in accordance with SEQ ID NO 8 or 10, beginning with amino acid 22 in claim 11 and adds no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

19. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavrovic et al. (PTO-892; Reference V) as evidenced by the specification on page 4, lines 1 and 19-22.

Gavrovic et al. teaches the isolated Sec c 4 protein from Secale cereale (In particular, abstract).

The specification on page 4 teaches that Sec c 4 is the Group 4 allergen isolated from *Secale cereale* having the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO:4. The reference teaches the same isolated allergen from the same source, so the resulting allergen must necessarily have the sequence of SEQ ID NO:2 or SEQ ID NO:4.

Claims 10-12 are included in this rejection because the recitation of the amino acid sequences in accordance with SEQ ID NO 2 and 4 in claim 10 and the amino acid sequences in accordance with SEQ ID NO 2 or 4, beginning with amino acid 23 in claim 11 and adds no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "as medicament" in claim 12 does not carry patentable weight per se. The claim reads on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL Accession No AJ862830 (Reference 7 on the IDS filed on 06/15/2008); EMBL Accession No AJ862831 (Reference 8 on the IDS filed on 06/15/2008); EMBL Accession No AJ862834 (Reference 9 on the IDS filed on 06/15/2008); EMBL Accession No AJ862832 (Reference 10 on the IDS filed on 06/15/2008); EMBL Accession No AJ862833 (Reference 11 on the IDS filed on 06/15/2008); and Gavrovic et al. (PTO-892; Reference V) each in view of WO 2004/000881 (Reference 2 on the IDS filed on 06/15/2006) and the corresponding U.S. Patent Application Publication 2006/0177470 A1 (PTO-892; Reference A).

EMBL Accession No AJ862830; EMBL Accession No AJ862831; EMBL Accession No AJ862834; EMBL Accession No AJ862832; EMBL Accession No AJ862833 and Gavrovic et al. have each been discussed *supra*.

The claimed invention differs from the prior art in the recitation of "a pharmaceutical composition comprising at least one polypeptide according to Claim 12 and optionally further active ingredients and/or adjuvants for the diagnosis and/or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved" in claim 13.

U.S. Patent Application Publication 2006/0177470 teaches the use of Group IV grass

pollen allergens and homologous allergens in other species for diagnosis and therapy of allergic diseases (In particular, paragraph [0047). The reference also teaches pharmaceutical compositions comprising these allergens that further comprise other active ingredients and adjuvants (In particular, paragraphs [0072]-[0076]).

It would have been obvious to one of ordinary skill in the art to use any of the allergens taught by EMBL Accession No AJ862830; EMBL Accession No AJ862831; EMBL Accession No AJ862834; EMBL Accession No AJ862832; EMBL Accession No AJ862833 and Gavrovic et al. in a pharmaceutical composition further comprising other active ingredients or adjuvants for diagnosis or therapy because WO 2004/000881 and the corresponding U.S. Patent Application Publication 2006/0177470 teach the use of Group IV grass pollen allergens and homologous allergens in other species for diagnosis and therapy of allergic diseases.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

22. No claim is allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Nora M. Rooney

Patent Examiner

Technology Center 1600

/Maher M. Haddad/

Primary Examiner, Art Unit 1644